

## § 520.905b

## 21 CFR Ch. I (4–1–05 Edition)

the indications provided in paragraph (d) of this section and for treating infections of stomach bot as provided in § 520.2520, have been shown to be compatible and not to interfere with one another.

[42 FR 59069, Nov. 15, 1977; 43 FR 12311, Mar. 24, 1978. Redesignated at 44 FR 1375, Jan. 5, 1979, and amended at 46 FR 29464, June 2, 1981; 47 FR 15327, Apr. 9, 1982; 48 FR 42809, Sept. 20, 1983; 49 FR 1983, Jan. 17, 1984; 53 FR 40058, Oct. 13, 1988; 59 FR 26943, May 25, 1994; 61 FR 29478, June 11, 1996; 63 FR 63983, Nov. 18, 1998; 66 FR 47960, Sept. 17, 2001; 68 FR 26205, May 15, 2003]

### § 520.905b Fenbendazole granules.

(a) *Specifications.* Each gram of granules contains 222 milligrams (mg) fenbendazole.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 5 mg/kilogram (kg) for large strongyles, small strongyles, and pinworms; 10 mg/kg for ascarids.

(ii) *Indications for use.* For the control of infections of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*).

(iii) *Limitations.* Sprinkle the appropriate amount of drug on a small amount of the usual grain ration. Prepare for each horse individually. Withholding feed or water is not necessary. Retreat in 6 to 8 weeks if required. Do not use in horses intended for food.

(2) *Dogs*—(i) *Amount.* 50 mg/kg daily for 3 consecutive days.

(ii) *Indications for use.* For the removal of ascarids (*Toxocara canis*, *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations.* Mix the appropriate amount of drug with a small amount of the usual food; dry dog food may require slight moistening to facilitate mixing. Medicated food must be fully consumed.

(3) *Zoo and wildlife animals*—(i) *Amount.* 10 mg/kg per day for 3 days.

(ii) *Indications for use.* For control of internal parasites of *Felidae* and *Ursidae* as follows:

(A) Lion (*Panthera leo*) and Tiger (*Panthera tigris*): Ascarid (*Toxocara cati*, *Toxascaris leonina*), Hookworm (*Ancylostoma* spp.).

(B) Cheetah (*Acinonyx jubatus*): Ascarid (*Toxocara cati*, *Toxascaris leonina*).

(C) Puma (*Felis concolor*), Panther (*Panthera* spp.), Leopard (*Panthera pardus*), Jaguar (*Panthera onca*): Ascarid (*Toxocara cati*, *Toxascaris leonina*), Hookworm (*Ancylostoma* spp.), Tapeworm (*Taenia hydatigena*, *T. krabbei*, *T. taeniaeformis*).

(D) Black Bear (*Ursus americanus*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*), Hookworm (*Ancylostoma caninum*), Tapeworm (*Taenia hydatigena*, *T. krabbei*).

(E) Polar Bear (*Ursus maritimus*) and Grizzly Bear (*Ursus horribilis*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*).

(iii) *Limitations.* Top dress or mix with a small portion of food. Must be fully consumed prior to feeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use 14 days before or during the hunting season.

[44 FR 1375, Jan. 5, 1979, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 50528, Nov. 2, 1983; 59 FR 35252, July 11, 1994; 66 FR 47960, Sept. 17, 2001; 67 FR 47450, July 19, 2002]

### § 520.905c Fenbendazole paste.

(a) *Specifications.* The product is an aqueous paste containing 10 percent fenbendazole.

(b) *Sponsor.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) (a) *Amount.* 2.3 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for a 1,100-pound horse). For foals and weanlings (less than 18 months of age), 4.6 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for each 550 pounds of body weight).

(b) *Indications for use.* For control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*),

and ascarids (*Parascaris equorum*) in horses.

(c) *Limitations.* Retreatment at intervals of 6 to 8 weeks may be required. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii)(a) *Amount.* 4.6 milligrams per pound of body weight (one 2.5-gram fenbendazole syringe for a 550-pound horse) daily for 5 days.

(b) *Indications for use.* For control of arteritis caused by the fourth stage larvae of *Strongylus vulgaris*.

(c) *Limitations.* Treatment should be initiated in the spring and repeated in 6 months. Do not use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of fourth stage larvae of *S. vulgaris*.

(iii)(a) *Amount.* 4.6 milligrams per pound of body weight (10 milligrams per kilogram) daily for 5 consecutive days.

(b) *Indications for use.* For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae in horses.

(c) *Limitations.* (Consult your veterinarian for assistance in the diagnosis, treatment, and control of encysted mucosal cyathostomes). Do not use in horses intended for food.

(2) *Beef and dairy cattle—(i) Amount.* Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) *Indications for use.* For the removal and control of lungworm (*Dictyocaulus viviparus*), barberpole worm (*Haemonchus contortus*), brown stomach worm (*Ostertagia ostertagi*), small stomach worm (*Trichostrongylus axei*), hookworm (*Bunostomum phlebotomum*), thread-necked intestinal worm (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and nodular worm (*Oesophagostomum radiatum*).

(iii) *Limitations.* Re-treatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Consult a vet-

erinarian for assistance in the diagnosis, treatment, and control of parasitism.

(e) *Special considerations.* Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (d)(1)(i) of this section and for treating infections of stomach bots as provided in § 520.2520.

[46 FR 32018, June 19, 1981, as amended at 47 FR 15327, Apr. 9, 1982; 49 FR 8433, Mar. 7, 1984; 50 FR 26358, June 26, 1985; 61 FR 29478, June 11, 1996; 63 FR 31624, June 10, 1998; 66 FR 47960, Sept. 17, 2001]

#### § 520.905d Fenbendazole powder.

(a) *Specifications.* (1) Each 2-ounce packet contains 2.27 grams (4 percent) of fenbendazole plus other inert ingredients.

(2) Each 4-ounce packet contains 1.7 grams (1.5 percent) of fenbendazole plus other inert ingredients.

(b) *Sponsors.* (1) See No. 057926 in § 510.600(c) of this chapter for use of the 4-percent product.

(2) See No. 017800 in § 510.600(c) of this chapter for use of the 1.5-percent product.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Conditions of use.* It is administered to swine as follows:

(1) *Amount.* 3 milligrams fenbendazole per kilogram body weight per day (1.36 milligrams per pound per day).

(2) *Indications for use.* For removal and control of large roundworms (*Ascaris suum*); lungworms (*Metastrongylus apri*); nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worms (*Hyostromylus rubidus*); whipworms (*Trichuris suis*); and kidneyworms (*Stephanurus dentatus*—mature and immature).

(3) *Limitations.* Thoroughly mix the contents of the packet(s) with swine ration and administer according to label directions. Feed as sole ration for 3 consecutive days. Can be fed to pregnant sows. No prior withdrawal of feed or water is necessary. Consult your